

## IN THE CLAIMS

1. (previously presented) A method for diagnosing a cancer in a mammal, comprising:  
detecting and measuring the hepsin gene copy number in a biological subject from a  
region of the mammal that is suspected to be precancerous or cancerous, thereby generating data  
for a test gene copy number; and

comparing the test gene copy number to data for a control gene copy number,  
wherein a detectable increase in amplification of the gene in the biological subject relative to the  
control indicates the presence of a precancerous lesion or a cancer in the mammal.

2. (currently amended) The method according to claim 1, wherein the biological subject  
~~is selected from the group consisting of ovarian tissue, prostate tissue, breast tissue, and lung~~  
~~tissue.~~

3. (currently amended) The method according to claim 1, wherein at least one of the  
data for the test gene copy number or the data for the control gene copy number are stored  
in a data storage medium an electronic or a paper format, wherein the electronic format is  
selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital  
versatile disk (DVD), memory card, memory chip, ROM, RAM, ROM or RAM, magnetic  
optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server;  
wherein the data is displayed, transmitted or analyzed via physical transfer, electronic  
transmission, video display, or telecommunication; wherein the data is compared and compiled  
at the site of sampling specimens or at a location where the data is transmitted.

4-8. (canceled).

9. (previously presented) A method for monitoring the efficacy of a therapeutic  
treatment regimen in a patient, comprising:

measuring the hepsin gene copy number in a first sample of precancerous or cancer cells obtained from a patient;

administering the treatment regimen to the patient;

measuring the hepsin gene copy number in a second sample of precancerous or cancer cells from the patient at a time following administration of the treatment regimen; and

comparing the gene copy number in the first and the second samples, wherein data showing a detectable decrease in the gene copy number levels in the second sample relative to the first sample indicates that the treatment regimen is effective in the patient.

10. (currently amended) The method according to claim 9, wherein the precancerous or cancer cells are obtained from ovarian tissue, prostate tissue, breast tissue, or and lung tissue.

11. (currently amended) The method according to claim 9, wherein data representing the hepsin gene copy number in at least one of the first and second samples are data from measuring or comparing the expression levels is stored in a data storage medium ~~an electronic or a paper format, wherein the electronic format is selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, ROM or RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server; wherein the data is displayed, transmitted or analyzed via physical transfer, electronic transmission, video display, or telecommunication; wherein the data is compared and compiled at the site of sampling specimens or at a location where the data is transmitted.~~

12. (currently amended) A method for diagnosing a breast cancer or a lung cancer in a mammal, comprising:

measuring ~~the~~ a test level of hepsin mRNA expression transcripts in a biological subject from a region of the mammal that is suspected to be precancerous or cancerous, ~~thereby generating data for a test level; and~~

comparing the test level to ~~data for a control level of hepsin mRNA expression,~~ wherein a detectable increase in the test level ~~of the biological subject~~ relative to the control level indicates the presence of a cancer or precancerous lesion in the mammal.

13. (canceled).

14. (currently amended) The method according to claim 12, wherein ~~the data representing at least one of the test and the control levels are data is stored in a data storage medium an electronic or a paper format, wherein the electronic format is selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, ROM or RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server; wherein the data is displayed, transmitted or analyzed via physical transfer, electronic transmission, video display, or telecommunication; wherein the data is compared and compiled at the site of sampling specimens or at a location where the data is transmitted.~~

15-21. (canceled).

22. (currently amended) A method for monitoring the efficacy of a therapeutic treatment regimen in a patient, comprising:

measuring a first expression level of at least one of hepsin mRNA or hepsin protein expression levels in a first sample of a biological subject comprising precancerous or cancer cells obtained from a patient;

administering the treatment regimen to the patient;

measuring a second expression level of at least one of hepsin mRNA or hepsin protein expression levels in a second sample of the biological subject precancerous or cancer cells from the patient at a time following administration of the treatment regimen; and

comparing at least one of hepsin mRNA or hepsin the first and second expression levels in the first and the second samples, wherein ~~data showing~~ a detectable decrease in the second expression level levels in the second sample relative to the first expression level first sample indicates that the treatment regimen effectively reduced the number of precancerous or cancer cells in the biological subject is effective in the patient.

23. (currently amended) The method according to claim 22, wherein the biological subject is precancerous or cancer cells are obtained from ovarian tissue, prostate tissue, breast tissue, or and lung tissue.

24. (currently amended) The method according to claim 22, wherein ~~the data from measuring or comparing representing at least one of the first and second expression levels are is stored in a data storage medium an electronic or a paper format, wherein the electronic format is selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, ROM or RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server;~~

~~wherein the data is displayed, transmitted or analyzed via physical transfer, electronic transmission, video display, or telecommunication; wherein the data is compared and compiled at the site of sampling specimens or at a location where the data is transmitted.~~

25-32. (canceled).

33. (currently amended) A method for diagnosing a breast cancer in a mammal, comprising:

detecting a test hepsin protein expression level by contacting a biological subject from a region of the mammal that is suspected to be precancerous or cancerous with anti-hepsin antibody, ~~thereby generating data for a test level, wherein hepsin is overexpressed in tumor cells compared to normal cells;~~ and

comparing the test hepsin protein expression level to a control hepsin protein expression level of a control biological subject ~~test level to data for a control level,~~ wherein a detectable increase in the test hepsin protein expression level ~~test level of the biological subject relative to the control hepsin protein expression level indicates the presence of a breast cancer or precancerous lesion in the mammal.~~

34. (currently amended) The method according to claim 33, wherein the biological subject is selected from the group consisting of ovarian tissue, prostate tissue, breast tissue, and lung tissue.

35. (currently amended) The method according to claim 33, wherein the data representing at least one of the test and control hepsin protein expression levels are stored in a data storage medium ~~an electronic or a paper format, wherein the electronic format is selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM or RAM, magnetic optical disk, tape, video,~~

video clip, microfilm, internet, shared network, and shared server; ~~wherein the data is displayed, transmitted or analyzed via physical transfer, electronic transmission, video display, or telecommunication; wherein the data is compared and compiled at the site of sampling specimens or at a location where the data is transmitted.~~

36-38. (canceled).

39. (currently amended) The method ~~methods~~ according to claim 1, wherein the detectable increase in amplification is about 2.5 fold.

40. (currently amended) The method ~~methods~~ according to claim 9, wherein the detectable decrease in the amplification is about 2.5 fold.

41. (currently amended) The method ~~methods~~ according to claim 12, wherein the detectable increase in the test level is about 5.0 fold.

42. (currently amended) The method ~~methods~~ according to claim 22, wherein the detectable decrease in the second expression level is about 5.0 fold.

43. (currently amended) The method ~~methods~~ according to claim 33, wherein the detectable increase in the test hepsin protein expression level is about 5.0 fold.

44. (new) The method of claim 1 wherein the mammal is a human.

45. (new) The method of claim 9 wherein the mammal is a human.

46. (new) The method of claim 12 wherein the mammal is a human.

47. (new) The method of claim 22 wherein the mammal is a human.

48. (new) The method of claim 33 wherein the mammal is a human.

49. (new) The method of claim 1 wherein the biological subject is prostate tissue.

50. (new) The method of claim 1 wherein the biological subject is breast tissue.

51. (new) The method of claim 1 wherein the biological subject is lung tissue.

52. (new) A method for diagnosing a cancer in a mammal, comprising:

determining a hepsin gene copy number in a biological subject from a region of the mammal which is suspected to be precancerous or cancerous, wherein amplification of the hepsin gene copy number indicates the presence of cancer or a precancerous lesion in the mammal.

53. (new) The method of claim 52 wherein the mammal is a human.

54. (new) The method of claim 52 wherein the biological subject is ovarian tissue.

55. (new) The method of claim 52 wherein the biological subject is prostate tissue.

56. (new) The method of claim 52 wherein the biological subject is breast tissue.

57. (new) The method of claim 52 wherein the biological subject is lung tissue.

58. (new) The method of claim 52 wherein data representing the hepsin gene copy number is stored in a data storage medium selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

59. (new) A method for diagnosing a cancer in a mammal, comprising:

determining a first indirect measure of hepsin gene copy number in a biological subject from a region of the mammal that is suspected to be precancerous or cancerous; and

comparing the first indirect measure to a second indirect measure of a control gene copy number in a control biological subject, wherein a detectable change in the first indirect measure relative to the second indirect measure indicates the presence of a precancerous lesion or a cancer in the mammal.

60. (new) The method of claim 59 wherein the first and second indirect measures are determined by real-time quantitative RT-PCR and the detectable change is a detectable decrease.

61. (new) The method of claim 59 wherein the first and second indirect measures are determined by fluorescence *in situ* hybridization (FISH) and the detectable change is a detectable increase.

62. (new) A method for monitoring the efficacy of a therapeutic treatment regimen in a patient, comprising:

determining a first indirect measure of hepsin gene copy number in a first sample of a biological subject comprising precancerous or cancer cells obtained from a patient;

administering the treatment regimen to the patient;

determining a second indirect measure of hepsin gene copy number in a second sample of the biological subject at a time following administration of the treatment regimen; and

comparing the first and second indirect measures, wherein a detectable change in the second indirect measure relative to the first indirect measure indicates that the treatment regimen effectively reduced the number of precancerous or cancer cells in the biological subject.

63. (new) The method of claim 62 wherein the first and second indirect measures are determined by real-time quantitative RT-PCR and the detectable change is a detectable decrease.

64. (new) The method of claim 62 wherein the first and second indirect measures are determined by fluorescence *in situ* hybridization (FISH) and the detectable change is a detectable increase.